REMARKS

On page 3 of the Office Action the Examiner objected to the specification because certain molecular weight ranges for polyethylene glycol were listed in the claims as originally filed, but not in the specification. Applicant has herein amended paragraph 0010 of the specification. Support for this amendment can be found in claim 4 of the published application as originally filed. No new matter has been added. Based on the above referenced amendment, it is requested that the objection be withdrawn.

On pages 3 to 4 of the Office Action the Examiner rejected claims 26, 27, 28 and 36 under 35 USC 112, first paragraph.

Reconsideration is requested.

The present specification at paragraphs 0010 and 0042-43 of the published application teaches polyethylene glycols having molecular weight ranges from about 100 to about 20,000, from about 1000 to about 10,000, and specifically polyethylene glycols with molecular weights of 200, 300, 400, 540 blend, 900, 1000, 1450, 3350, 4000, 4600, and 8000. These polyethylene glycol ranges are also disclosed in the Examples in paragraphs 0056 to 0064. Applicant submits that the polyethylene glycol weight ranges of from about 100 to about 1600, from about 1600 to about 5000, and from about 5000 to about 20,000 are inclusive of the weight ranges disclosed in the present application and are reflective of the embodiments disclosed in the application as originally filed. Applicant submits that these ranges do not constitute new matter and requests that the present 112, first paragraph rejection be withdrawn.

On pages 4-6 of the Office Action the Examiner rejected claims 1-10, and 25-36 under 103(a) as being unpatentable over United States Patent No. 4,151,273 (hereinafter Riegelman et al.) in view of United States Patent No. 4,098,802 (hereinafter Van der Vies).

Reconsideration is requested.

Applicant wishes to point out for clarity that there is no claim 9, and there was no claim 9 filed in the original application and therefore the currently pending claims are claims 1-8, 10 and 25-36.

Claims 1, 25 and 36 have been amended to correct a typographical error. Specifically, "is" is not "its" for the phrase "a therapeutically effective amount of testosterone, or ~~is~~ its

pharmaceutically acceptable salts or esters, or a mixture thereof". No new matter has been added. Further, claim 30 has been amended to recite that "the fifth polyethylene glycol has a different molecular weight than the first, second, third and fourth polyethylene glycols". No new matter has been added. Support for these amendments can be found at least in Examples 5 and 8 of the present application.

Claims 1-8 and 10

Riegelman et al. only discloses the use of different concentrations and different molecular weight ranges for polyethylene glycol in combination with gris (griseolfuvin). The remaining examples, namely, hydrocortisone acetate, prednisolone acetate, 17-methyltestosterone, or digitoxin, all contain 95% polyethylene glycol 6000. *See* Riegelmnan et al. at col. 3, line 20 to col. 4, line 25. Because Riegelman only discloses embodiments containing greater than 90% polyethylene glycol with active other than gris, it teaches away from dosage forms containing between 30% w/w and 80% w/w testosterone as recited in the claims of the present application. Additionally, the only examples which were shown to release the active ingredient were listed in Table 1 in column 5 of Riegelman et al. All of the examples in Table 1 contain gris. Therefore, there is no disclosure in Riegelman et al. of a dosage form containing between 30% w/w and 80% w/w polyethylene glycol that exhibits a release that would provide a therapeutically effective testosterone serum level to a patient as recited in the claims of the present application.

Additionally, Van der Vies does not disclose any dosage forms containing between 30% w/w and 80% w/w polyethylene glycol and therefore it does not alleviate the deficiencies of Riegelman et al. While Van der Vies recites some possible dosage strengths of testosterone derivatives, it does not provide any guidance towards using specific weight ranges of specific molecular weight polyethylene glycols as recited in the claims of the present application.

Moreover, there is no disclosure in Van der Vies or Riegelman et al. to provide a testosterone serum level ranging from about 15 ng/dl to about 1200 ng/dl. While the Applicant acknowledges that the Examiner believes this to be an inherent quality a dosage form containing between 2.5 and 45 mg of testosterone, Applicant submits that the Examiner has not pointed to any evidence in the cited prior art to substantiate this claim. Neither of the cited prior art references demonstrate working examples of testosterone dosage forms containing between 30% w/w and 80% w/w polyethylene glycol, and therefore combining the references, changing the active

ingredients, changing the concentration of polyethylene glycol and molecular weight of the polyethylene glycol cannot be assumed to produce a specific testosterone serum level, even when the dosage forms contain similar total active to the cited prior art. This would require improper hindsight analysis, using knowledge only contained in the present application.

Claims 25-36

With specific regard to claims 25-36 neither Reigelman et al. nor Van der Vies teach or suggest the use of multiple polyethylene glycol carriers possessing different molecular weights in a single formulation. More specifically, the cited prior art does not teach or suggest the use of three, four or five separate polyethylene glycol carriers, each having different molecular weights being employed to provide therapeutic levels of the testosterone active ingredient.

Therefore, based on the above, it is requested that the 103(a) rejection be withdrawn.

Based upon the above remarks and amendments, Applicant respectfully submits that Claims 1-8, 10 and 25-36 are allowable and that the present application is in proper form for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,

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